

Appl. No.: 10/767,471
Atty. Docket: CI.1505ORD

REMARKS

Status of the Claims

Claims 1-4, 6-26 are pending. Claim 5 was previously canceled. Claims 8-22, 25, and 26 were withdrawn from further consideration as being drawn to non-elected subject matter as a result of a restriction requirement.

By entry of this amendment, claims 2-4, 6-26 have been canceled without disclaimer or prejudice. Applicants reserve the right to pursue the subject matter encompassed in the canceled claims in subsequent continuation or divisional applications.

Claims 1 has been amended by this amendment. New claims 27-65 have been added. Thus, claims 1, and 27-65 are currently under examination.

No new matter has been added by this amendment.

Support for amended claims and the new claims can be found in the specification including pages 2, 9, 22, 119, 122, the Examples section, Table 1, Table 2, Table 5, Table 6 and the Sequence Listing. Note that SEQ ID NO: 10739 is the genomic sequence where SEQ ID NO: 36673 (201 nucleotides) can be found.

This amendment adds, changes and/or deletes claims in the instant application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, are presented with an appropriate defined status identifiers. See 37 C.F.R. §1.121(c).

Claim Objections

The Examiner objected to claims 1-4, 6, 7, 23 and 24 as they allegedly recite non-elected subject matter.

By entry of this amendment, the objections are obviated, and should be withdrawn.

Rejections under 35 USC §112, second paragraph, indefiniteness

The claims are rejected under 35 USC §112, second paragraph, as being allegedly indefinite. Applicants respectfully traverse.

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By entry of this amendment, the claims now recite the SNP location within SEQ ID NO: 36673, and are clearly defined as to the subject matter they pertain to. Thus, the Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 USC §112, first paragraph, written description

The claims are rejected under 35 USC §112, first paragraph, for allegedly being not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

As amended, the claims now specify one SNP hCV16021387, rs2476601, within SEQ ID NO: 36673, which is associated with an altered risk of an autoantibody-positive autoimmune disease.

Therefore, the rejections under 35 USC §112, first paragraph, for allegedly lack of adequate written description have been overcome. The Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 USC §112, first paragraph, enablement

The claims are rejected under 35 USC §112, first paragraph, for allegedly being not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse.

As amended, the claims recite one specific SNP located within SEQ ID NO: 36673, and are now directed to human subjects, and to the risk of a particular kind of autoimmune disease (autoantibody-positive) within the human subjects.

It is well known that the Examiner bears the initial burden to make a *prima facie* case that the claims are enabled in the specification. As stated in the MPEP, "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)". MPEP §2164.04. A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement

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requirement of 35 U.S.C. §112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. MPEP §2164.04.

The Examiner cited several references such as *Harrison et al.*, *Lee et al.*, *Begovich et al.*, and *Criswell et al.*, in support of the rejections. However, a closer reading of the references shows that they support the instantly claimed invention, which encompasses SNPs that are associated with risks of developing autoantibody-positive autoimmune diseases in human subjects. For example, both *Criswell* and *Begovich* state that the PTPN22 SNP is associated with several autoimmune diseases with the common, prominent feature linking these diseases being that they are autoantibody-positive. See *Criswell*, at page 562, right column, at page 568, left column, and at page 568, right column. See also *Begovich*, at pages 185 through 186.

In addition, the Examiner's attention is directed to *Van Oene et al.*, attached in the enclosed Form PTO/SB/08B. *Van Oene et al.*, Arthritis and Rheumatism, 2005; 52: 1993-98. This reference provides convincing data showing that the OR associated with the PTPN22 risk alleles was essentially the same in RF- patients and RF+ patients. *Van Oene et al.*, at pp. 1995-96. Thus, there is evidence that the PTPN22 SNP is associated with an autoimmune disease in both RF+ and RF- patients. However, in the interest of expediting the prosecution of the instant application, applicants have amended the claims such that they are now directed towards those patients who are autoantibody-positive, such as RF+. The specification as filed, in light of the references discussed herein, provides ample teachings and disclosure for the enablement of the amended claims. Applicants reserve the right to pursue the subject matter not encompassed in the current set of amended claims in subsequent continuation or divisional applications.

Thus, the *prima facie* case of lack of enablement has not been made, and that applicants' instant invention relating to SNP rs2476601 being associated with autoantibody-positive autoimmune diseases in human subjects is indeed enabled by the specification as filed.

Therefore, the rejections under 35 USC §112, first paragraph, for allegedly lack of enablement have been overcome with the claims amendment and in light of the remarks above. The Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 USC §102(b)

Claims 23 and 24 are rejected under 35 USC §102(b) for allegedly being anticipated by GenBank GI 14970654 (17-July-2001).

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By entry of this amendment, claims 23 and 24 have been cancelled without disclaimer or prejudice, thus making this rejection moot. The Examiner is respectfully requested to withdraw this rejection.

In conclusion, in light of the amendments and remarks above, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly requested.

The Examiner is invited to contact the undersigned via telephone if a phone interview would expedite the prosecution of the instant patent application.

Respectfully submitted,

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